IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BOBBY SHULL, M.D.

Introduction and Summary

Only one set of plaintiffs in this wave of cases, Teresa and Giuseppe Sciumbata, designated Dr. Bobby Shull as a general causation expert, and Dr. Shull intends to provide general opinions about Mrs. Sciumbata's Prolift +M device. *See* Ex. A; Ex. B, Prolift +M General Report. Defendants Ethicon, Inc., Ethicon, LLC and Johnson & Johnson's (collectively "Ethicon's") brief in this wave of cases is very similar to their brief submitted for the Wave 3 cases with the following exceptions: (a) in Section II, Ethicon requests that the Court preclude Dr. Shull from comparing Prolift +M with traditional surgical procedures consistent with recent rulings by this Court and others; and (b) in Section V, this brief highlights a *Daubert* ruling governing Dr. Shull by the United States District for the Northern District of Illinois as it relates to a Wave 1 case remanded from this Court (*see Walker v. Ethicon, Inc.*, 2017 WL 2992301 (N.D. Ill. June 22, 2017)). For the reasons set forth below, the Court should preclude Dr. Shull from:

- Criticizing Ethicon's warnings and labels, because he is not qualified to do so, and his opinions are irrelevant;

- Suggesting that traditional surgical procedures are a safer alternative to Prolift +M, because his opinions are irrelevant;
- Suggesting that other synthetic mesh devices have fewer complications, because his opinions are irrelevant and/or unreliable;
- Providing design and development opinions, because such opinions are beyond his expertise;
- Speculating about the duties owed by a medical device manufacturer, such as research/testing, adverse event reporting, and training, because such opinions are irrelevant and beyond his expertise; and
- Testifying about other matters that are outside of his expertise as a urogynecologist and/or that are otherwise improper.

All of these opinions are inadmissible under Rules 702 and 703 and the *Daubert* standard governing expert witness testimony.

BACKGROUND

Dr. Shull is a urogynecologist in Temple, Texas. Ex. A to Ex. B, Prolift +M Report, curriculum vitae. Although Dr. Shull uses TVT for the surgical treatment of stress urinary incontinence, he has never tried using Prolift for the surgical treatment of pelvic organ prolapse. Ex. D, Shull Mar. 10, 2016 Dep. Tr. 13:16-22; Ex. E, Shull Mar. 15, 2016 Dep. Tr. 39:19-21. Dr. Shull is not personally critical of all uses of polypropylene mesh for pelvic reconstruction, but he prefers to use native tissue repair. *Id.* at 45:8-11, 49:23-50:9.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should exclude Dr. Shull's warning opinions, because he is not qualified and certain of his opinions are irrelevant.

Dr. Shull has freely admitted that he is not an expert in developing warnings and labels for medical devices: "I have never developed a warning or a label. I don't intend to do that. And I don't know the process for doing it, so I would not claim to be an expert in that area." Ex. F, Shull Feb. 2013 Dep. Tr. 115:1-7; *see also id.* at 64:12-16, 348:11-350:25. Nonetheless, Dr. Shull is prepared to offer opinions about the adequacy of the warnings for Prolift +M. Ex. B, Prolift +M Report at 3, 10-12.

Based on this same testimony and his failure to address what the product warnings should have said, this Court has precluded Dr. Shull from testifying about the adequacy of product warnings for other pelvic mesh medical devices. *See Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013). Noting that "[w]hile an expert who is an obstetrician and gynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise about what information should or should not be included in an IFU," the Court has further found that Dr. Shull "does not possess [such] additional expertise." *In re: Ethicon, Inc. Pelvic Repair Sys. Produc. Liab. Litig.*, 2016 WL 458220, at *3 (S.D. W. Va. Sept. 1, 2016). The Court should follow and apply those rulings to this case for the same reasons and preclude Dr. Shull from expressing any opinions about the adequacy of the warnings for Prolift.

This includes preventing Dr. Shull from testifying that "Ethicon did not inform doctors as to which patients were poor candidates for the Prolift procedure." Ex. B, Prolift +M Report at 12. To the extent that Dr. Shull intends to testify about those patient populations of which Mrs. Sciumbata is not a member, any such testimony is irrelevant and unhelpful to the jury and therefore inadmissible. *See* Fed. R. Evid. 402, 702. Moreover, Dr. Shull's opinions are merely a

narrative summary of Ethicon documents (*see, e.g.*, Ex. B, Prolift +M Report at 12), and as this Court and many others have recognized, "[h]aving an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony." *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008). The Court should preclude Dr. Shull from doing so here.

In *Huskey,* Dr. Rosenzweig sought to testify that Ethicon inappropriately promoted the product as appropriate for all patients. 29 F. Supp. 3d at 705. This Court, however, found that "much of this opinion is not relevant to [the plaintiff's] case and should be excluded." *Id.* The Court went further and also precluded Dr. Rosenzweig from testifying about the appropriateness of the product to the plaintiff's specific population. *See id.* The Court reasoned that Dr. Rosenzweig's opinion was merely based upon his review of a document, and "[t]he jury is capable of reading that document itself." *Id.*

Based on the statements set forth on pages 12-13 of Dr. Shull's report, Ethicon anticipates that Plaintiffs will attempt to elicit the same type of testimony from Dr. Shull that the plaintiffs in *Huskey* sought to elicit from Dr. Rosenzweig. For the same reasons as *Huskey*, the Court should preclude Dr. Shull from offering such testimony here.

II. The Court should preclude Dr. Shull from testifying that traditional surgical procedures are a safer alternative to Prolift +M, because his opinions are irrelevant.

Dr. Shull opines that native tissue repair procedures, such as anterior colporrhaphy, are a safer alternative to Prolift +M. Ex. B, Prolift +M Report, pp. 5-6, 13-15. Any alleged comparative benefits of traditional approaches to treat pelvic organ prolapse are not relevant to Plaintiffs' design defect claims, because these approaches are not a medical device and do not entail altering the design of the device. Ethicon challenged these opinions in its Wave 1 briefing, and the Court determined that "[t]he relevance of this expert testimony is better decided on a

case-by-case basis," and therefore, reserved ruling. *In re Ethicon, Inc.*., 2016 WL 4582220, at *2. Since that time, however, the Court has issued several rulings suggesting that this should be revisited. First, the Court has determined that opinions about alternative procedures are not a case-specific issue, but instead, an issue within "the province of a general causation expert—not a specific causation expert." *Brooks v. Ethicon, Inc.*, No. 2:12-cv-02865, Mem. Op. at 4 (S.D.W. Va. July 12, 2017), Ex. C hereto.

Second, this Court recently precluded one of Plaintiffs' other general causation experts, Dr. Nathan Goodyear, from offering very similar opinions. In *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017), the Court stated:

> Ethicon argues that Dr. Goodyear's opinions regarding *alternative procedures* are irrelevant to the question of whether a safer alternative design of a product exists. Ethicon states, "[A] medical device *product is* not defective in design simply because alternative surgical and nonsurgical *procedures* may exist." Defs.' Mem. Supp. Mot. 4. ***I agree with Ethicon that alternative procedures/ surgeries do not inform the issue of whether an alternative design for a product exists.*** Accordingly, Ethicon's Motion on this point is **GRANTED** and Dr. Goodyear's alternative procedures testimony is **EXCLUDED**.

(Emphasis added).

Third, in *Mullins v. Johnson & Johnson*, 2017 WL 711766, at *2 (S.D.W. Va. Feb. 23, 2017), the Court explicitly found that "[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." The Court reasoned that "other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries." *Id.* (emphasis in original). The Court further found that the "the plaintiffs must provide evidence of an alternative, feasible design for the *product* at issue," which entails "provid[ing] sufficient evidence to identify a comparable product or design concept, whether the *design features* of the comparable product or the *design concept* existing at the time of the [device's] manufacture . . .

." *Id.* at *3 (emphasis in original). *See also Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim).[1]

Relying on this reasoning, an Illinois federal district court recently precluded Dr. Shull from testifying that traditional procedures are safer alternatives to the Prolift +M device, stating "[t]he Court agrees with the MDL Court and Defendants that evidence regarding a different surgical procedure not involving mesh is irrelevant to the existence of a safe alternative design for the product at issue in this case." *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *2 (N.D. Ill. June 22, 2017). The court held as such even though the Illinois law applied in that case did not require the plaintiff to prove the existence of a safer alternative. *See Dunning v. Dynegy Midwest Gen., Inc.*, 2015 IL App. (5th) 140168, ¶66, 33 N.E.3d 179, 197-98 (2015).

Here, under the law of Pennsylvania—where Mrs. Sciumbata received her implant and the only state law applicable in this wave of cases with respect to Dr. Shull's general opinions—"[t]he determination of whether a product was negligently designed turns on whether "an alternative, feasible, safer design would have lessened or eliminated the injury plaintiff suffered." *Berrier v. Simplicity Mfg.*, 563 F.3d 38, 64 (3d Cir. 2009) (quoting *Habecker v. Clark Equipment Co.*, 36 F.3d 278, 281 (3d Cir.1994)). The notion that traditional surgical procedures are safer alternatives to Ethicon's devices "really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the medical device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999)). Thus, Dr. Shull's opinions about these traditional surgical procedures are not changes to the design feature or the design concept of the

[1] These rulings are in accord with others. *See, e.g., Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *3 (E.D. La. Mar. 30, 2000) (holding that while there existed "alternative techniques" for the mesh surgery, such techniques did not prove an "alternative design" for the polypropylene surgical mesh product). They reflect a general principle of product liability law that applies whenever a safer alternative design is claimed.

device at issue; instead, his opinions would eliminate the device in its entirety. *See also Nease v. Ford Motor Co.*, 848 F.3d 219, 234 (4th Cir. 2017) (finding that controlling case law may "only be read to require the production of evidence on reasonable alternative design, to gauge what 'should have been'") (quoting Restatement (Third) of Torts: Products Liability § 2, Reporter's Note (1998)).

III. The Court should preclude Dr. Shull from suggesting that other synthetic mesh devices have fewer complications, because his opinions are irrelevant and/or unreliable.

In his report, Dr. Shull states that "[s]maller pore, heavier weight meshes, like Gynemesh PS, are thought to intensify" adverse reactions as compared to lighter weight, more macroporous meshes. Ex. B, Prolift +M Report at 7. Ethicon challenged this same assertion in its Wave 1 briefing on the basis that it perceived that Dr. Shull was unreliably suggesting that a device with larger pore, lighter weight mesh would offer a safer, feasible alternative to Prolift. The Court, however, found that Dr. Shull's afore-quoted statement is "not about the overall balance between safety and efficacy or the appropriateness of an alternative design; Dr. Shull was merely opining on adverse reactions." *In re: Ethicon*, 2016 WL 458220, at *3.

If, in fact, Dr. Shull has not disclosed any opinions that suitable alternative device designs were available, then Dr. Shull's opinions about other devices or potential devices are not relevant. It is one thing for Dr. Shull to provide opinions about adverse reactions caused by Prolift +M. On the other hand, Ethicon would be prejudiced should Dr. Shull be allowed to compare Prolift +M's adverse reactions to the adverse reactions in other medical devices if Dr. Shull is not offering an opinion (much less a reliable opinion) that those other devices were a suitable alternative.

Should the Court construe Dr. Shull's assertion as suggesting that other synthetic mesh devices offered safer, feasible alternatives to Prolift +M, the Court should preclude any such testimony as unreliable. Even if a device with lighter-weight/more macroporous mesh would have led to few complications, neither Dr. Shull nor any other expert can reliably show that such a device would have been as effective as Prolift +M in treating pelvic organ prolapse. *See Conklin v. Novartis Pharmas. Corp*, 2012 WL 4127295 (E.D. Tex. 2012).

Dr. Shull has suggested that the mesh in Prolift +M would have fewer adverse reactions if it had been made of larger pore, lighter weight mesh. But Dr. Shull points to no studies, testing, or other scientific evidence whatsoever that those devices would have been equally effective as a treatment for prolapse if the mesh had those characteristics. Nor does Dr. Shull point to any evidence that, had the mesh had such characteristics, there would not be an increased risk of other adverse events.

Dr. Shull cannot—and does not—identify the polypropylene volume at which efficacy can be obtained and adverse events avoided. At most, he merely suggests that some form of mesh may exist in which the volume of polypropylene is low enough to avoid adverse events but high enough to be sufficiently effective. What that volume is, he does not know. And whether this hypothetical alternative exists, he does not know. In this context, his opinions are entirely speculative, and they should be excluded.

IV. The Court should preclude Dr. Shull from providing design and development opinions, because he is unqualified to do so.

Dr. Shull has no experience in the design, development, or manufacturing process of any medical devices, and he never received any documents from Ethicon referencing the design and development of its devices. *See* Ex. E, Shull Mar. 15, 2016 Dep. Tr. at 63:12-14, 82:5-12. Dr. Shull, nevertheless, asserts in his reports that "[f]rom a clinical perspective, Ethicon did not

exercise due diligence in the design and development of the" devices at issue. Ex. B, Prolift +M Report at 3. Aside from the fact that this interjects an irrelevant, improper legal conclusion concerning "due diligence," which is a phrase that is vague, ambiguous, and without any meaning as used in this context, Dr. Shull cannot purport to weigh in on these topics "[f]rom a clinical perspective," because the design and development of pelvic mesh medical devices is beyond his expertise as a pelvic surgeon.

This Court has previously precluded Dr. Shull and other pelvic surgeons from offering similar opinions. *See, e.g., Cisson*, 948 F. Supp. 2d at 612-13 (precluding Dr. Shull from providing similar testimony); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 561-62 (S.D. W. Va. 2014) (finding that another pelvic surgeon, Dr. Blaivas, was not qualified to testify about product design). In, adjudicating Ethicon's challenge to these same opinions in the Wave 1 cases, the Court indicated that it did not construe Dr. Shull's reports as "express[ing] any opinions about the process of designing a product." *In re: Ethicon*, 2016 WL 4582220, at *3. Because Dr. Shull's report in this wave of cases is identical to his reports in the Wave 1 cases, the Court should make the same finding here. Alternatively, Ethicon respectfully requests that the Court preclude Dr. Shull from providing such opinions on the basis that he is unqualified to do so.

V. The Court should not allow Dr. Shull to speculate about the duties of a medical device manufacturer.

Because Dr. Shull is not qualified to provide expert opinions about what duties Ethicon owed as a manufacturer of FDA-cleared medical devices, the Court should preclude him from offering opinions set forth throughout his report that criticizes Ethicon for allegedly failing to comply with certain legal duties allegedly owed by a medical device manufacturer.

A. Research/Testing

In his report, Dr. Shull faults Ethicon for allegedly not performing certain testing and conducting studies. *See, e.g.*, Ex. B, Prolift +M Report at 3, 24-26. The Court should exclude these opinions, which are of questionable relevance, because Dr. Shull is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed.

As an initial matter, a lack of testing or a flaw in the design process is not, standing alone, a design defect. *See, e.g., Green v. General Motors Corp.*, 310 N.J. Super. 507, 529 (App. Div. 1998) ("[A] product that is not defective and has not been tested at all remains free of a defect"). The "failure to test" claim here should be seen for what it is—a transparent attempt to shift the burden to the *defendant* to prove the absence of the defect when the plaintiff cannot carry her burden to prove the existence of a defect.

Even if the degree of testing were somehow relevant,[2] Dr. Shull does not have specialized knowledge about the testing that medical device manufacturers like Ethicon supposedly should have performed. Dr. Shull lacks a basic familiarity with product testing. Ex. F, Shull Feb. 2013 Dep. Tr. 81:10-21, 138:6-17, 144:22-145:1. He acknowledged that he has no experience in developing medical devices. Ex. E, Shull Mar. 15, 2016 Dep. Tr. 63:12-14, 82:5-7. Dr. Shull's resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000).

[2] *See In re: Ethicon*, 2016 WL 4582220, at *5 ("I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research . . .").

Because Dr. Shull has no relevant experience, he is unable to identify a single rule or regulation that would require Defendants to conduct different testing. *See* Ex. B, Prolift +M Report at 3, 24-26. Moreover, Dr. Shull does not identify *any* basis or reason for these opinions, as he must. Instead, his opinion apparently is based purely on unscientific personal, subjective belief. *See Daubert*, 509 U.S. at 590 ("[T]he word 'knowledge' [in Rule 702] connotes more than subjective belief or unsupported speculation").

Further, a fundamental problem with Dr. Shull's opinion that Ethicon should have conducted additional testing and studies before marketing the devices is that Dr. Shull can only speculate about what those results would have shown. Thus, as noted by one court, "imposition of liability for breach of an independent duty to conduct long-term testing, where the causal link to the known harm to plaintiff is the *unknown outcome of testing that was not done*, would be beyond the pale of any California tort doctrine we can identify." *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1486 (1999) (emphasis in original).

This Court has consistently precluded other surgeons from testifying about this issue. In its Wave 1 rulings, the Court found that "[t]here is no indication that Dr. [Bruce] Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500765, at *5 (S.D.W. Va. Aug. 26, 2016); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp.3d 691, 705 (S.D.W. Va. July 8, 2014) (finding that "there is no indication that [plaintiff's pelvic surgeon expert] has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D.W. Va. Apr. 28, 2015) (finding that because pelvic surgeon "has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his

opinion falls short of Federal Rule of Evidence 702 and cannot be admitted"). Further, the Court has determined that "[w]hether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct." *Bellew v. Ethicon, Inc.*, 2014 WL 12685965, at *9 (S.D. W. Va. Nov. 20, 2014).

Recently, another federal district court, on remand from this Court, agreed with this Court's reasoning and precluded Dr. Shull from testifying about research and testing, finding that "Plaintiffs have not shown that Dr. Shull is qualified to testify regarding the standard of care for medical device testing," and that his opinions about the extent of testing "would merely address facts found in corporate documents." *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *5 (N.D. Ill. June 22, 2017). *See also In re: Silicone Gel Breasts Implants Prod. Liab. Litig.*, 318 F. Supp. 2d 879, 901-02 (C.D. Cal. Apr. 22, 2004) (finding that a chemist was not qualified to criticize defendants' alleged lack of testing and noting that "Plaintiff proffers no evidence that [the expert] has any experience developing an implantable medical device for general use or that he has any foundational knowledge about what standard practices exist in the industry in this regard"). For these same reasons, the Court should preclude Dr. Shull from offering such testimony here.

B. Adverse Event Reporting

Dr. Shull also claims that "Ethicon did not systematically monitor their products or evaluate physician feedback." Ex. B, Prolift +M Report at 3. Dr. Shull's experience as a surgeon does not qualify him to render opinions on adverse event reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g., In re Diet Drugs*, 2001 WL 454586, at *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon's

opinions regarding adverse event reporting because surgeon had "no experience or expertise in . . . adverse event reporting" and based his opinions on personal belief rather than reliable methodology).

In its Wave 1 ruling, this Court found that "opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED.**" *In re: Ethicon, Inc.*, 2016 WL 4582220, at *4. The Court should do so again here and clarify that all of Dr. Shull's adverse event reporting opinions are excluded, regardless of whether they are specific to compliance with FDA regulations. In *Walker, supra*, the Illinois federal district court prevented Dr. Shull from providing similar criticisms of Ethicon's response to adverse event reports. *Walker*, 2017 WL 2992301, at *6. According to the court, "[s]imilar to the MDL Court excluding Dr. Shull's opinion regarding product testing or clinical trials in another case based on a lack of experience with such matters, *see Carlson*, 2015 WL 1931311, at *15, the Court excludes Dr. Shull's opinion regarding the standard of care for adverse event reporting because Plaintiffs have not demonstrated that Dr. Shull has relevant experience to testify as an expert about this matter." *Id.* The court further "note[d] that Dr. Shull cannot serve as a conduit for corporate information by testifying about the extent of Defendants' adverse event reporting." *Id.*

C. Training

Dr. Shull claims that Ethicon generally did not provide appropriate training to physicians. Ex. B, Prolift +M Report at 3. First, Plaintiffs cannot show that Ethicon owed any duty to train physicians. *See, e.g., Woodhouse v. Sanofi-Aventis U.S. L.L.C.*, 2011 WL 3666595, at *3 (W.D. Tex. June 23, 2011); *Adeyinka v. Yankee Fiber Control, Inc.*, 564 F. Supp. 2d 265, 286 (S.D. N.Y. 2008); *Lemon v. Anonymous Physician*, 2005 WL 2218359, at *2 (S.D. Ind. Sept. 12, 2005). Even if Ethicon owed any such duty (which it does not), physician training "seem[s] to

say very little about the state of the product (i.e., whether or not it was defective) when it went on the market." *In re: Ethicon*, 2016 WL 4582220, at *5.

In any event, Dr. Shull, as a urogynecologist with no experience working for a medical device manufacturer, is not qualified to opine about the level of training that a manufacturer is required to provide. Dr. Shull does not know what FDA rules, if any, apply to this subject, what the consequences of failing to comply with FDA rules are, and/or what the legal effect of noncompliance is. Further, Dr. Shull's criticism of Ethicon's training is unreliable, because he does not explain the basis for his opinions.[3]

Further, these opinions are irrelevant insofar as Dr. Shull has not claimed that Mrs. Sciumbata's implanting physician was inadequately trained. *See Cisson*, 948 F. Supp. 2d at 614 (excluding similar opinions about training under similar circumstances). Consistent with the Illinois federal court's ruling in *Walker, supra*, the Court should determine that any of Dr. Shull's opinions about training should be limited to a discussion of "the risks of implanting mesh and whether Defendants' product materials raise those risks, but he may not offer testimony about 'what information should or should not be included in an [Instructions for Use]' or other similar materials." *Walker*, 2017 WL 2992301, at *6.

VI. The Court should not allow other opinions beyond Dr. Shull's expertise.

Finally, consistent with its prior rulings, the Court should preclude Dr. Shull from: (a) speculating about Ethicon's alleged knowledge and corporate conduct;[4] (b) testifying about a medical condition that Mrs. Sciumbata's medical expert has not competently testified that the Plaintiff has sustained or likely will sustain; (c) stating legal conclusions;[5] (d) accusing Ethicon

[3] Dr. Shull's opinions are not based on his personal experience, because he has never undertaken any training from Ethicon concerning use of its devices. Ex. E, Shull Mar. 15, 2016 Dep. Tr. 40:13-18.

[4] *See, e.g.*, Ex. B, Prolift +M Report at 9-13, 24-26, 28-44.

[5] *See id.* at 3.

of failing to comply with FDA requirements;[6] (e) providing marketing opinions;[7] and (f) setting forth a narrative summary of Ethicon documents.[8] *See, e.g., In re: Ethicon*, 2016 WL 4582220, at *4-5; *Cisson*, 948 F. Supp. 2d at 611, 614; *Huskey*, 29 F. Supp. 3d at 703.

CONCLUSION

For the foregoing reasons, the Court should limit Dr. Shull's testimony in these cases and preclude Dr. Shull from opining or testifying about any of the foregoing matters because his opinions are irrelevant and unreliable or he is unqualified to opine about the subject matter.

Respectfully Submitted,

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[6] *See id.* at 10.
[7] *See id.* at 3, 13.
[8] *See, e.g., id.* at 11-13, 29-44.

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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